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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,926	09/09/2003	Paul D. Corl	33483/US/ENB	3127

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EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/658,926	CORL ET AL.	
	Examiner	Art Unit	
	KAREN E. TOTH	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-29 and 56-79* is/are pending in the application.

4a) Of the above claim(s) *66 and 67* is/are withdrawn from consideration.

5)☒ Claim(s) *70-73 and 77-79* is/are allowed.

6)☒ Claim(s) *25-29,56-65,68,69,74 and 75* is/are rejected.

7)☒ Claim(s) *76* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/9/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. Claims 25, 26, 28, 29, 63, 64, 68, 69, 74, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel (US Patent Application Publication 2003/0050547) in view of Markle (US Patent 5596988), Webber (US Patent 6616614), and Ushizawa (US 4861454).

Regarding claim 25, Lebel discloses a probe comprising a cannula (element 12) with proximal (element 14) and distal (element 18) extremities, where the distal extremity is adapted to be inserted in a patient's blood vessel (paragraph [0030]) and contains an oxygen sensor assembly that provides an electrical signal when the cannula is disposed in the blood (element 20; paragraphs [0030], [0032]), and where the proximal extremity carries a connector (element 16); the distal extremity is adapted to slidably travel through an introducer when being inserted into the vessel (figure 9; step 110; paragraphs [0058]-[0059]), and the cannula and connector are sized such that the introducer may be slid off the proximal extremity and cannula after the distal extremity has been inserted (figure 9; step 112; paragraphs [0058]-[0059]). The Examiner notes that, though an introducer is mentioned in the claim, it is not actually part of the claimed apparatus, and the probe of Lebel merely needs to be able to work with any device used as an introducer. Lebel does not disclose a preferred

diameter range for the cannula, a carbon dioxide sensor in addition to the oxygen sensor, or the sensor assembly comprising proximal and distal sensors where each sensor comprises a reference electrode extending around insulation surrounding a working electrode, with the working electrode of the distal electrode, or a conductor connected to it, passing through the insulating layer surrounding the proximal electrode.

Markle teaches a probe for ascertaining characteristics of blood comprising a cannula having a diameter between 0.010 and 0.035 inches (column 5, lines 62-63), and a plurality of gas sensors, including those for carbon dioxide and oxygen in the distal extremity of the cannula (column 6 lines 1-3), in order to accurately monitor a patient's blood characteristics in small vessels.

Webber teaches a sensor assembly for ascertaining blood characteristics comprising a distal sensor (elements 77, 81, 82) and a proximal sensor (elements 76, 87, 88), where the distal sensor has a working electrode (element 81) that is covered with insulation (column 5, lines 32-35) and a reference electrode that extends around the working electrode (element 82 - figure 11), and the working electrode's components pass through the proximal sensor and its insulation (figure 11), in order to conserve space in the device.

Ushizawa also teaches a sensor assembly for ascertaining blood characteristics where the sensor has a working electrode (element 3) covered by insulation (element 4, 5) and a reference electrode that extends around the working electrode's insulation (element 7), in order to conserve space in the device.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel with an additional gas sensor for oxygen and sized the system to have an external diameter between 0.010 and 0.035 inches, as taught by Markle, in order to monitor multiple components of blood in small vessels, and further including both a distal and a proximal sensor, with the sensors' reference electrodes extending around insulated working electrodes, as taught by Webber and Ushizawa, in order to conserve space in the device, where Ushizawa suggests forming Webber's proximal sensor to match the distal one, since Ushizawa teaches forming all blood gas sensors as overlapping electrodes.

The Examiner notes that, in the specification of the present application, it appears that one of the proximal and distal sensors is the carbon dioxide sensor, and the other is the oxygen sensor. However, the claim is directed merely to an assembly comprising unspecified sensors, which means that any combination of additional sensors (such as Webber's working and reference sensing electrodes) may be included.

Regarding claim 26, Lebel further discloses using an introducer with the device (paragraphs [0058]-[0059]).

Regarding claims 28 and 29, Lebel further discloses the connector having a cylindrical portion (figure 1) and an electrical contact (paragraph [0031]), and the probe having a conductor extending from the electrical contact to the sensor

and seated flush with the cylindrical portion (element 62; paragraphs [0042] and [0046]).

Regarding claims 63 and 64, Lebel discloses using gas-permeable material to form the cannula (element 66; paragraphs [0044], [0054]).

Regarding claims 68 and 69, Lebel in view of Markle and Webber discloses all the elements of the claimed invention, as described above, except for the system further comprising a display module with a connector for connecting to the probe's connector, allowing communication between the probe and display, and where the display module includes a band that makes it adaptable for securing to a patient's wrist.

Webber further teaches a display module (element 22) that connects to and communicates with the implantable blood probe (elements 23, 24, 51), and comprises a band (element 28) that allows the display to be mounted on the patient's arm in a location of the user's choosing, such as the wrist (figure 1), in order to provide as much mobility to the patient as possible while still accurately monitoring the blood gas. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel in view of Markle, Webber, and Ushizawa with a display module connected to the connector of the probe and secured to the patient's wrist, as taught by Webber, in order to provide mobility while monitoring blood gas.

Regarding claims 74 and 75, Ushizawa further teaches forming the insulating layer as a tube and having at least two layers (elements 4 and 5) – see figure 11 – in order to conserve space while retaining the component's insulative

properties. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Lebel, Markle, Webber, and Ushizawa with the insulating layer in the form of a tube and having at least two layers, as taught by Ushizawa, in order to conserve space while retaining insulative properties.

3. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle, Webber, and Ushizawa, as applied above, and further in view of Schulman (US Patent 5497772).

Lebel in view of Markle, Webber, and Ushizawa discloses all the elements of the claimed invention, as described above, except for the introducer being a needle. Schulman teaches a system for implanting a blood component sensor comprising an introducer needle that is used to place a sensor probe (column 10, lines 10-24), in order to ease the insertion of the sensor. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel in view of Markle, Webber, and Ushizawa with an introducer needle, as taught by Schulman, in order to ease insertion of the sensor.

4. Claims 56-58 and 60-61 rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle, Webber, and Ushizawa, as applied above, and further in view of Cheney (US Patent 5391250).

Regarding claim 56, Lebel in view of Markle, Webber, and Ushizawa discloses all the elements of the claimed invention, as disclosed above, except for the probe comprising a flex circuit extending through the cannula, having a distal portion with two electrodes, and conductors running between a proximal end of the cannula and the electrodes, where the electrodes are at least part of the gas sensor assembly. Lebel further discloses the gas sensor comprising electrodes (elements 36) on a substrate (element 30), with conductors that are used to connect the electrodes to proximal portions of the sensor (elements 44). Lebel does not disclose the substrate being flexible (that is, the sensor assembly being a flex circuit).

Cheney discloses forming a gas sensor assembly using a flex circuit (element 10) comprising a distal portion with two electrodes (elements 24) and conductors (elements 14) connecting the electrodes to a proximal portion of the device (figure 1), so that the sensor is both accurate and durable. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel in view of Markle, Webber, and Ushizawa with a flex circuit for sensing gas, as taught by Cheney, so that the sensor is both accurate and durable.

Regarding claims 57 and 58, Lebel further discloses a sealed chamber in the cannula containing an electrolyte solution and the electrodes (paragraph [0054]-[0056]).

Regarding claim 60, Cheney further discloses the proximal portion of the flex circuit serving as a connector (elements 26), in order to reduce the number

of components and electrical connections in the system. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the probe of Lebel in view of Markle, Webber, Ushizawa, and Cheney with the proximal end of the flex circuit serving as the connector, as taught by Cheney, in order to reduce the number of components and connections in the system.

Regarding claim 61, Lebel further discloses the electrodes being pads formed on the exposed surface of the circuit (figure 2A).

5. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle, Webber, Ushizawa, and Cheney, as applied to claims 56-58 and 60-61 above, and further in view of Schulman (US Patent Application Publication 2001/0051768).

Lebel in view of Markle, Webber, Ushizawa, and Cheney discloses all the elements of the claimed invention, as described above, except for the probe further comprising a second sealed chamber housing two additional electrodes and an electrolyte solution.

Schulman teaches an implantable probe for sensing components of blood comprising a plurality of sealed chambers (in this case, the combination of a "sensor assembly" and window), each having two electrodes (elements 12, 14, 16, 18) and an electrolyte solution (element 22) (paragraphs [0026]-[0027], 0031], [0034-0037], [0062]), in order to allow sensing from a variety of areas within the patient's body without requiring multiple probes. It would have been

obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel in view of Markle, Webber, Ushizawa, and Cheney with an additional chamber having electrodes and an electrolyte solution, as taught by Schulman, in order to allow sensing from a variety of areas within the patient's body without requiring multiple probes.

6. Claim 62 rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle, Webber, Ushizawa, and Cheney, as applied to claims 56-58 and 60-61 above, and further in view of Pantages (US Patent Application Publication 2001/0029337).

Lebel in view of Markle, Webber, Ushizawa, and Cheney discloses all the elements of the claimed invention, as described above, except for the probe comprising adhesive to hold the flex circuit in place in the cannula. Pantages teaches an implantable blood characteristic probe comprising a flex circuit held in place in a cannula using adhesive (paragraph [0084]), in order to ensure that the flex circuit does not move. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the probe of Lebel in view of Markle, Webber, Ushizawa, and Cheney with adhesive securing the flex circuit within the cannula, as taught by Pantages, in order to ensure that it does not move.

7. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle, Webber, and Ushizawa, as applied above, and further in view of Kirsch (US Patent 6503225).

Lebel in view of Markle, Webber, and Ushizawa discloses all the elements of the claimed invention, as described above, except for the pas permeable material being polymethylpentene. Kirsch teaches an implantable probe system having a gas permeable coating of polymethylpentene (column 4, lines 43-45), since use of polymethylpentene as a gas permeable polymer coating is well known in the implantable probe art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the probe of Lebel in view of Markle, Webber, and Ushizawa with a polymethylpentene coating, as taught by Kirsch, since it is a well-known gas permeable polymer coating material.

Allowable Subject Matter

8. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to anticipate or make obvious the inventions of claims 70-73 and 77-79, including, *inter-alia*, a probe comprising a gas-permeable cannula with proximal and distal extremities, where the distal extremity is adapted to be inserted in a patient's blood vessel and contains an sensor assembly with oxygen and carbon dioxide sensors that provides an electrical signal when the cannula is disposed in the blood, and where the

proximal extremity carries a connector; the distal extremity is adapted to slidably travel through an introducer when being inserted into the vessel, and the cannula and connector are sized such that the introducer may be slid off the proximal extremity and cannula after the distal extremity has been inserted. The sensor assembly further comprises an insulating conduit, first and second working electrodes, first and second reference electrodes, and first, second, third and fourth conductors extending through the cannula to the connect to the electrodes in the sensing assembly, where the insulating conduit serves as a support for the first reference electrode and as a conduit for the conductor coupled to the second reference electrode.

9. Claim 76 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the device of claim 76, including, *inter-alia*, a probe for ascertaining blood characteristics that may be passed through an introducer and comprising a cannula, and an oxygen and carbon dioxide sensor assembly, where the sensor assembly comprises proximal and distal sensors, each sensor having working and reference electrodes, where each sensor's working electrode is covered by an insulating layer and the corresponding reference electrode extends at least partially around the insulating layer, the distal working electrode, or a conductor in contact with it, extends through the insulating layer surrounding the proximal working electrode,

and at least one of the working electrodes extends at least partially around an insulating layer.

Response to Arguments

10. Applicant's arguments with respect to claims 25-29, 56-65, 68, 69, and 74-76 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735